IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

NOVO NORDISK A/S AND NOVO NORDISK INC., Plaintiffs, vs. RAPID WEIGHT LOSS AND ESTHETICS CENTER, INC., Defendant.	Civil Action No. 4:25-CV-446-JD

DEFENDANT RAPID WEIGHT LOSS AND ESTHETICS CENTER, INC.'S MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM AND MEMORANDUM IN SUPPORT

Pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, Defendant Rapid Weight Loss and Esthetics Center, Inc. ("Rapid Weight Loss"), through its undersigned counsel, submits its Motion to Dismiss for Failure to State a Claim and Memorandum in Support respectfully requesting that this Court dismiss all claims that Plaintiffs assert against Rapid Weight Loss. In support of its Motion, Rapid Weight Loss states as follows:

PRELIMINARY STATEMENT

Plaintiffs Novo Nordisk A/S and Novo Nordisk, Inc.'s ("Plaintiffs") Complaint alleges false and misleading advertising and promotion in violation of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B). This claim fails, however, because (1) Rapid Weight Loss's advertising statements on their face are true, and there are no allegations that any misleading statements have caused actual consumer deception nor harmed Plaintiffs; (2) Plaintiffs' claim of implied Food and Drug Administration ("FDA") approval is insufficient to sustain a Lanham Act claim because private parties cannot use the Lanham Act to enforce the Food, Drug and Cosmetic Act ("FDCA"); and (3) the FDCA precludes a Lanham Act claim where, as here, FDA must use its particular expertise to resolve such a claim. Plaintiffs' deceptive and unfair

trade practices claim in violation of the South Carolina Unfair Trade Practices Act ("SCUTPA"), S.C. Code Section 39-5-20 is predicated on the same allegations as Plaintiffs' Lanham Act claims and must fail for those same reasons. Further, Plaintiffs' SCUTPA claim is preempted by the FDCA as FDA has sole authority to enforce the FDCA.

Because Plaintiffs' claims are insufficient on their face, precluded, and preempted, this Court should dismiss Plaintiffs' Complaint in its entirety with prejudice.

FACTUAL BACKGROUND

Plaintiffs manufacture pharmaceuticals, including three prescription-only, FDA-approved drug products containing semaglutide as the main molecule and active pharmaceutical ingredient ("API") for weight management: Ozempic, Rybelsus, and Wegovy. Compl. ¶ 2. Defendant Rapid Weight Loss's website references compounded semaglutide medications. *Id.* ¶ 31. Compounding is a traditional component of the practice of pharmacy and involves the "process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient."[1] Compounded drugs are used when a physician determines that a commercially available drug is inappropriate or unavailable to properly treat a patient.[2] Compounded drugs, thus, fill the gaps sometimes left by FDA-approved drugs to ensure proper patient treatment.

To preserve the vital role compounded drugs have in individualized patient care, Congress exempted compounded drugs from the new drug approval requirements.[3] Compounded drugs, therefore, do not undergo FDA approval.[4] Yet, compounded drugs remain a well-recognized tool for patient treatment. In other words, compounding is legal and a vital component of the drug

[1] *Thompson v. W. States Med. Ctr.* 535 U.S. 357, 360-361 (2002)
[2] *Id*. at 361.
[3] *See* 21 U.S.C. § 353a(a); *see also* 21 U.S.C. § 353b(a).
[4] *Nexus Pharm., Inc. v. Cent. Admixture Pharm.*, 48 F.4th 1040, 1042 (9th Cir. 2022) ("Compounding pharmacies do not need FDA approval as a manufacturer of a new drug does.").

supply chain. Thus, many of the assertions in Plaintiffs' Complaint regarding alleged safety concerns are wholly irrelevant and unnecessary (and likely included to suggest that by merely selling these products, compounders put the public at risk—which is false). Ignoring the voluminous extraneous material in Plaintiffs' Complaint, Plaintiffs' only two legal claims are both premised on allegations that Rapid Weight Loss's marketing statements are false, misleading and/or likely to confuse consumers under federal and state law. Plaintiffs' Complaint is premised exclusively on the following two website statements:

> **Semaglutide Weight loss Results:**
>
> Clinical studies have shown that Semaglutide can lead to significant weight loss in people with obesity. In a study published in the New England Journal of Medicine (Feb. 2021), participants who received Semaglutide **lost an average of 15% of their body weight** over a 68-week period, compared to 2.4% for those receiving a placebo. Semaglutide is administered as a subcutaneous injection once a week. Like all medications, it can cause side effects and the dose is titrated up monthly to help avoid this. Common side effects include nausea, vomiting, constipation and diarrhea. These symptoms usually go away on their own, but if they persist or become severe, it is important to speak with our healthcare provider.

Complaint ¶ 46 & Ex. A.

> **Semaglutide Injections for Rapid Weight Loss Now Available!**
>
> Semaglutide (generic for Ozempic) is a medication that is gaining popularity for its use in weight loss.
>
> Clinical studies show that once weekly injections of Semaglutide reduces appetite and cravings, improves blood sugar control, aids in weight loss and reduces excess body fat including belly fat.
>
> It works by stimulating insulin secretion and reducing glucagon secretion in the pancreas, which helps to lower blood sugar levels. It also slows down the rate at which food is digested, which helps to reduce blood sugar spikes after meals.

Id. ¶ 49 & Ex. B. In essence, Plaintiffs rely on these two statements to support their Lanham Act and SCUTPA claims because the statements allegedly:

- describe the medications referenced on Rapid Weight Loss's website in a misleading way because these compounded medications are not the same as Plaintiffs' Ozempic (Compl. ¶ 44);

- imply falsely that the referenced compounded medications are subject to clinical studies, trials, and testing that result in the same therapeutic outcomes as Ozempic (*id.* ¶¶ 45-47);
- suggest that the referenced "semaglutide" contained in the compounded medications is the same "semaglutide" contained in Ozempic, but it is not because the processes Ozempic and the compounded medications undergo are different (*id.* ¶¶ 38, 48, 52, 53);
- use "Ozempic" to imply falsely that these compounded medications are FDA-approved (*id.* ¶¶ 49-50, 52-53); and
- are likely to expose patients to unnecessary risk because patients will mistakenly believe that these compounded medications are FDA-approved (*id.* ¶ 56).

In sum, Plaintiffs allege Rapid Weight Loss is engaging in false or misleading advertising because Rapid Weight Loss is advertising compounded medications (1) as if they are Ozempic; and (2) to be as safe, pure, and FDA-approved as Ozempic.

LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient ***factual matter***, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L.Ed.2d 868 (2009) (*quoting Bell Atlantic v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L.Ed.2d 929 (2007)) (emphasis added). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

The court must determine whether the factual allegations in a complaint state a plausible claim for relief based on "judicial experience and common sense." *Id.* at 679, 129 S. Ct. 1937. While the court "should view the complaint in a light most favorable to the plaintiff," *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir. 1993), "the court '***need not accept the [plaintiff's] legal conclusions*** drawn from the facts,' nor need it 'accept as true unwarranted inferences, unreasonable conclusions, or arguments.'" *Wahi v. Charleston Area Med. Ctr., Inc.*, 562 F.3d 599, 615 n.26 (4th Cir. 2009) (quoting *Kloth v. Microsoft Corp.*, 444 F.3d 312, 319 (4th Cir. 2006))

(emphasis added).

"It is … well established that in considering a Rule 12(b)(6) motion, courts may consider 'documents incorporated into the complaint by reference … as well as those attached to the motion to dismiss, so long as they are integral to the complaint and authentic.'" *Leask v. Robertson*, 589 F. Supp. 3d 506, 517-18 (D.S.C. 2022) (quoting *United States ex rel. Oberg v. Pa. Higher Educ. Assistance Agency*, 745 F.3d 131, 136 (4th Cir. 2014) (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007) and *Philips v. Pitt Cnty. Mem'l Hosp.*, 572 F.3d 176, 180 (4th Cir. 2009))). Here, the court can consider Rapid Weight Loss's statements, both referenced in and appended to Plaintiffs' Complaint, in evaluating whether Plaintiffs' Complaint meets the appropriate pleading standards. Compl. ¶¶ 46, 49 and Exs. A & B.

ANALYSIS

I. PLAINTIFFS' COMPLAINT FAILS TO STATE CLAIMS UNDER THE LANHAM ACT AND SCUTPA

A. Lanham Act and SCUTPA Elements and Pleading Standards

A plaintiff who asserts a claim under the Lanham Act must establish: (1) the defendant made a false or misleading description of fact or representation of fact in a commercial advertisement about his own or another's product; (2) the misrepresentation is material, in that it is likely to influence the purchasing decision; (3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience; (4) the defendant placed the false or misleading statement in interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products. *Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 272 (4th Cir. 2002). With respect to the first element, a plaintiff must show an alleged statement or representation is either "false on its face or, although literally true, likely to mislead and to confuse consumers given the merchandising context." *Scotts Co.*, 315 F.3d at

272-73.

To establish a SCUTPA claim, a plaintiff must show "(1) that the defendant[s] engaged in an unlawful trade practice, (2) that the plaintiff suffered actual, ascertainable damages as a result of the defendant[s'] use of the unlawful trade practice, and (3) that the unlawful trade practice engaged in by the defendants had an adverse impact on the public interest." *Scurmont LLC v. Firehouse Restaurant Grp., Inc.*, Nos. 4:09-cv-00618-RBH, 4:09-cv-00673-RBH, 2010 WL 11433199, at *4 (D.S.C. May 19, 2010) (alterations in original) (citation omitted). It is common for plaintiffs to allege that the unlawful trade practice is trademark infringement or false advertising. Following this playbook, Plaintiffs make no new factual allegations merely asserting "the above-described acts of Defendant constitute unfair methods of competition . . . by using false or misleading descriptions of fact and false or misleading representations of fact in its commercial advertising or promotion." Compl. ¶¶ 73-74. In other words, the predicate acts constituting an "unlawful trade practice" alleged by Plaintiffs are the same allegations which support its Lanham Act false advertising claims.

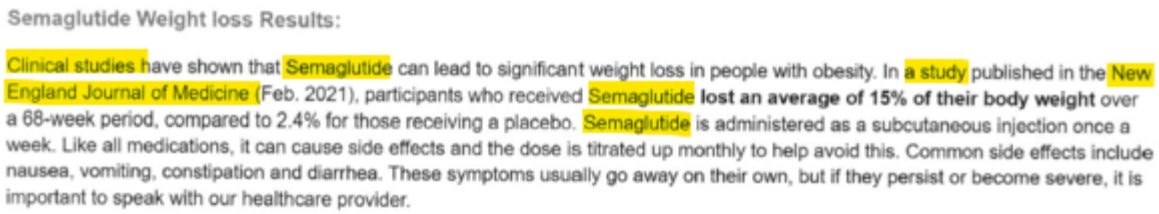
1. Rapid Weight Loss's Statements Are Not Literally False on their Face

"In analyzing whether an advertisement . . . is literally false [i.e., the advertisement is false on its face], a court must determine, first, the unambiguous claims made by the advertisement . . ., and second, whether those claims are false." *PBM Prods., LLC v. Mead Johnson & Co.*, 639 F.3d 111, 120 (4th Cir. 2011) (ellipses in original) (quoting *Scotts Co.*, 315 F.3d at 274). "A literally false message may be either explicit or conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated." *Id.*

When "evaluating claims asserting literal falsity by necessary implication, courts have emphasized the limits of this theory of liability, holding that not 'all messages implied by an advertisement will support a finding of literal falsity.'" *Design Res., Inc. v. Leather Indus. of Am.*, 789

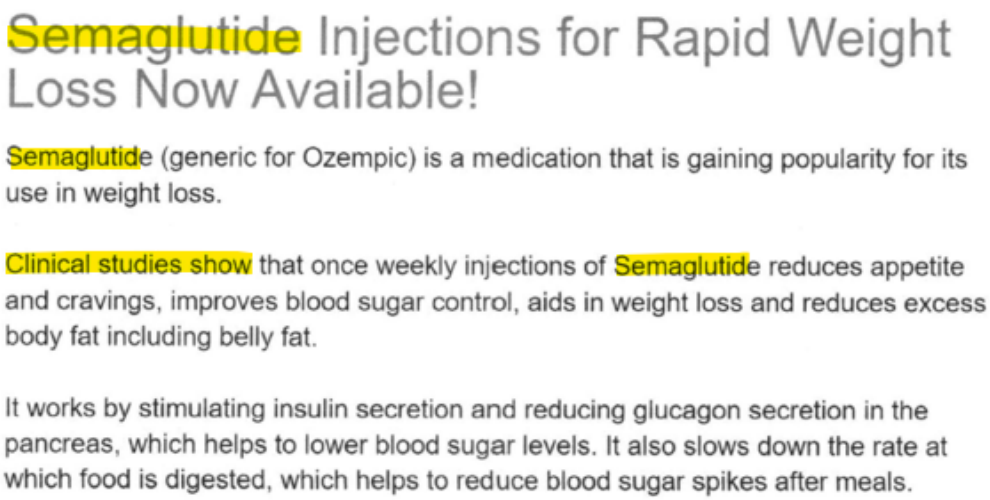
F.3d 495, 502 (4th Cir. 2015) (quoting *Clorox Co. P.R. v. Proctor & Gamble Com. Co.*, 228 F.3d 24, 35 (1st Cir. 2000)). "The greater the degree to which a message relies upon the viewer or consumer to integrate its components and draw the apparent conclusion, . . . the less likely it is that a finding of literal falsity will be supported." *Id.* (ellipsis in original) (quoting *Clorox Co. P.R.*, 228 F.3d at 35). Further, "[c]ommercial claims that are implicit, attenuated, or merely suggestive usually cannot fairly be characterized as literally false." *Id.* (quoting *Clorox Co. P.R.*, 228 F.3d at 35). "Where the advertisement is literally false, a violation may be established without evidence of consumer deception." *Id.* at 273 (citing *Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave.*, 284 F.3d 302, 310-11 (1st Cir. 2002)).

Here, Plaintiffs take issue with two of Rapid Weight Loss's statements on its website, in sum asserting that Rapid Weight Loss falsely advertises the compounded medications it references (1) as if they are Plaintiffs' Ozempic; and (2) to be as safe, pure, and FDA approved as Plaintiffs' Ozempic. Plaintiffs allege these statements are misleading because in both instances, Rapid Weight Loss is referring to Ozempic and studies conducted regarding Ozempic, rather than the compounded medications. *Id.* ¶¶ 46-50.



Semaglutide Weight loss Results:

Clinical studies have shown that Semaglutide can lead to significant weight loss in people with obesity. In a study published in the New England Journal of Medicine (Feb. 2021), participants who received Semaglutide **lost an average of 15% of their body weight** over a 68-week period, compared to 2.4% for those receiving a placebo. Semaglutide is administered as a subcutaneous injection once a week. Like all medications, it can cause side effects and the dose is titrated up monthly to help avoid this. Common side effects include nausea, vomiting, constipation and diarrhea. These symptoms usually go away on their own, but if they persist or become severe, it is important to speak with our healthcare provider.



Semaglutide Injections for Rapid Weight Loss Now Available!

Semaglutide (generic for Ozempic) is a medication that is gaining popularity for its use in weight loss.

Clinical studies show that once weekly injections of Semaglutide reduces appetite and cravings, improves blood sugar control, aids in weight loss and reduces excess body fat including belly fat.

It works by stimulating insulin secretion and reducing glucagon secretion in the pancreas, which helps to lower blood sugar levels. It also slows down the rate at which food is digested, which helps to reduce blood sugar spikes after meals.

Compl. Exs. A & B.

But Rapid Weight Loss's website advertisements are not false on their face. As for Plaintiffs' allegations that Rapid Weight Loss refers to compounded medications "as if they were Ozempic," Rapid Weight Loss includes explicit citation to the referenced clinical study in the New England Journal of Medicine, and does not say or imply that Rapid Weight Loss hosted, conducted, funded, or developed the referenced clinical study.[5] The statements on their face refer to ***a*** clinical study or studies conducted on semaglutide—which it is lawfully permitted to do, and is on its face not plausibly misleading or false.

As Plaintiffs' complaints that Rapid Weight Loss's statements refer to compounded medications as if they are as safe, pure, and FDA-approved as Ozempic is, Plaintiffs conflate "semaglutide"—which is an active pharmaceutical ingredient ("API")[6]—and Plaintiffs' FDA-approved drug product ***containing*** semaglutide, Ozempic. In context, Rapid Weight Loss's statements plainly and repeatedly refer to semaglutide, an API, and ***not*** to Ozempic. As Plaintiffs well know, an API itself does not receive FDA approval; rather, only a final drug product containing an API can. Indeed, nowhere in the challenged

[5] *See* John P.H. Wilding, D.M., et al., Once-Weekly Semaglutide in Adults with Overweight or Obesity, 384 N. Engl. J. Med. 11, 989 (Feb. 2021).

[6] "API" means "*any substance that is intended for incorporation into a finished drug product* and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. [API] ingredient does not include intermediates used in the synthesis of the substance." 21 U.S.C. § 207.1 (emphasis added).

statements do the words "FDA" or "FDA approved" even appear.

2. Plaintiffs' Complaint Alleges No Facts to Support Customer Confusion

In the absence of literal falsity, it is the plaintiff's burden in a Lanham Act case to show that the challenged statements are nevertheless misleading or confusing. If a plaintiff's "theory of recovery is premised upon a claim of implied falsehood, a plaintiff must demonstrate, by extrinsic evidence, that the challenged [advertisements] tend to mislead or confuse consumers." *Scotts*, 215 F.3d at 273 (citing *Johnson & Johnson * Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 297 (2d Cir. 1992)). At the pleading stage, this requirement means that a plaintiff's complaint must plausibly allege that the website statements are implied falsehoods that actually deceived customers. *Scotts Co.*, 315 F.3d at 276; *Am. Bd. of Internal Med. v. Rushford*, 114 F.4th 42, 66 (1st Cir. 2024) (requiring plaintiffs to make some allegations of actual consumer deception or intentional deception to state a legally sufficient claim for relief at the pleading stage). Plaintiffs normally meet this requirement by including reference to a consumer reaction survey in the complaint. *Scotts Co*., 315 F.3d at 276.

But here, Plaintiffs' Complaint provides no allegations at all in support of any actual deception or confusion, and instead merely make only conclusory recitations of the elements of a false advertising claim. *See, e.g.*, *Vincent v. Utah Plastic Surgery Soc'y*, 621 F. App'x 546, 550 (10th Cir. 2015) ("Plaintiffs' complaint contains no such factual allegation or any other specific factual allegation on the issue of actual consumer deception [and] [a]ny assertions in their complaint on public confusion are mere speculation."). The sole materials referenced in and provided with the Complaint are the challenged statements themselves, which have already been shown above to be not false on their face. These, conclusory allegations and recitations of claim elements regarding "confusion" are not sufficient to state a claim under the Lanham Act, and therefore, Plaintiff's Lanham Act claim should be dismissed, as well as its derivative SCUTPA claim.

Similarly, Plaintiffs' allegations that they have both suffered and will continue to suffer injuries, including injury to Plaintiffs' business reputation, are wholly conclusory and lack reference to any plausible supporting facts. *See* Compl. ¶ 66. In *Vincent v. Utah Plastic Surgery Soc'y*, 621 F. App'x 546 (10th Cir. 2015), plaintiff made a similar conclusory allegation: "Plaintiffs have been and will continue to be damaged as a result of Defendants' false statements by the resultant market confusion, by disruption of Plaintiffs' relationships with its customers, loss of potential customers, by diversion of Plaintiffs' customers to Defendants, and by damage to Plaintiffs' goodwill and reputations as competent and reliable cosmetic surgeons." *Id.* at 550. Finding the plaintiff's allegation insufficient, the Tenth Circuit Court of Appeals upheld the dismissal of a false advertising claim. *Id.* Here, Plaintiffs provide even less detail concerning how they were allegedly injured and basically recite the elements of a Lanham Act and SCUTPA claim. Therefore, Plaintiff's Lanham Act claim and its derivative SCUTPA claims should also be dismissed on this additional basis.

II. PLAINTIFFS' LANHAM ACT CLAIMS PREMISED ON RAPID WEIGHT LOSS IMPLYING "FDA APPROVAL" ALSO FAIL AS A MATTER OF LAW

Rapid Weight Loss's website statements do not claim that the compounded medications have FDA approval. Plaintiffs' false advertising Lanham Act claim, therefore, relies on the theory that, through the two website statements excerpted above, Rapid Weight Loss *implies* that the compounded medications have FDA approval. This claim fails as a matter of law because false advertising Lanham Act claims based on allegations of implied governmental approval are insufficient where the allegation relies on implied governmental approval alone. *See Mylan*, 7 F.3d at 1139 (holding that merely placing a drug product on the market does not imply FDA approval and finding that a conclusion to the contrary would permit Mylan to use the Lanham Act to privately enforce the FDCA); *Impact Applications, Inc. v. Conclusion Mgmt., LLC*, No. GJH-19-3108, 2021 WL 978823, at *6 (D. Md. Mar. 16, 2021) (expanding *Mylan* and dismissing plaintiff's false advertising Lanham Act claim based on defendant's

allegedly false and misleading statements implying that their products "ha[d] been reviewed or approved by [ ] FDA when they ha[d] not" and noting that "allowing a Lanham Act claim to proceed where a plaintiff does not point to any statement or representation in the defendants' advertising [explicitly] declaring FDA approval or review . . . would in effect, allow the plaintiff to use the Lanham Act as a vehicle by which to enforce the [FDCA]").

Further, Plaintiffs' claim that Rapid Weight Loss implies that semaglutide is generic for Ozempic constitutes a false or misleading statement of FDA approval, *see* Compl. ¶¶ 49-50, is unsupported by case law and precluded by the FDCA. *Ethex Corp. v. First Horizon Pharm. Corp.*, 228 F. Supp. 2d 1048 (E.D. Mo. 2002) is instructive here. In *Ethex*, two pharmaceutical companies, Ethex and First Horizon, manufactured competing lines of prescription prenatal vitamins—PRENATE (Ethex) and PreCare Prenatal (First Horizon). *Ethex*, 228 F. Supp. 2d at 1050. Neither product required FDA approval before being marketed. *Id.* at 1052. Ethex brought a Lanham Act claim against First Horizon, alleging that First Horizon illegally listed its prenatal vitamins as "generic" versions of PRENATE in pharmaceutical drug databases that pharmacists use to fill prescriptions. *Id.* at 1051. The thrust of Ethex's argument was that First Horizon called its vitamins "generic" to PRENATE when they are not, and that First Horizon purposefully called them "generics" to induce pharmacists to substitute First Horizon's products for Ethex's. *Id.* at 1052. Ethex thus claimed First Horizon was taking a "'free ride' on [Ethex's] goodwill associated with PRENATE." *Id.*

The court concluded that Ethex was using this Lanham Act claim as a vehicle to improperly bring a private cause of action under the FDCA. *Id.* Central to its conclusion, the *Ethex* court reasoned the following:

> The touchstone of [Ethex]'s argument focuses on the fact that the "generic" implies FDA endorsement and certain FDA-defined concepts. See [Ethex]'s Answer and Counterclaims ¶ 43 (unless a drug has an approved ANDA, it cannot be properly and correctly represented to be generic to another drug), ¶ 57 (the term generic as

> used in the pharmaceutical industry presupposes FDA approval.), ¶ 63 (marketing vitamins as generic infers equivalence and interchangeability). [Ethex] argues that pharmacists, upon seeing [First Horizon's] version marketed as generic, were confused into believing that they could lawfully substitute [First Horizon's] version of the drug. ***But the pharmacists could only be confused if "generic" is taken as an implicit representation that the product meets FDA standards of bioequivalence and therapeutic equivalence. The decisions in this area have refused to allow plaintiffs to state a claim based on implicit representations of FDA approval; this Court thinks it inappropriate, then, to sustain a Lanham Act claim based on a representation which somehow implied FDA definitions.***

Id. at 1055 (emphasis added). Thus, the court dismissed Ethex's Lanham Act claim and held that an implied governmental approval is the type of claim "better left to [ ] FDA who has the expertise in enforcing and interpreting its own complicated regulations." *Id.* A district court in this circuit further clarified that express or implied claims of generic or pharmaceutical equivalence are precluded where there is some indication that FDA approval is needed to make an equivalency claim. *Cf. Pediamed Pharm., Inc. v. Breckenridge Pharm., Inc.*, 419 F. Supp. 2d 715, 725 (D. Md. 2006) (articulating that "express or implied claims of generic or pharmaceutical equivalence [are] not precluded where [, among other things,] *there was no indication that FDA approval is needed to make a claim of equivalency*") (emphasis added).

As in *Ethex*, the crux of these Plaintiffs' claims relies on the theory that "generic" implies FDA approval, and the express language of the Complaint attempts to privately enforce the FDCA. Like Ethex's claims that "the term generic as used in the pharmaceutical industry presupposes FDA approval," and marketing drug products "as generic infers equivalence and interchangeability," *see Ethex*, 228 F. Supp. 2d at 1055, so too, do Plaintiffs here allege that Rapid Weight Loss's "representations characterizing Ozempic as a mere 'brand name' of 'semaglutide' are misleading and falsely indicate that other 'semaglutide' medicines have been reviewed or approved by [ ] FDA[,]" *see* Compl., ¶ 50.

Here, Plaintiffs' Lanham Act claim is explicitly premised on allegations of implied FDA approval. Vast portions of Plaintiffs' Complaint reference the compounded medications' lack of

FDA approval and lack of studies and research to prove their safety, effectiveness, and quality compared to Ozempic. *See* Compl. ¶¶ 5, 8-9, 16-17, 32, 35-50, 52-53, 56, 61-62, 74. But Plaintiffs' Complaint does not (because it cannot) contain any allegations that Rapid Weight Loss made any express representation on its website (or otherwise) that the referenced semaglutide was FDA-approved. Plaintiff's claim, therefore, entirely relies on Rapid Weight Loss's website statements implying that the semaglutide being made available to its patients is FDA-approved. As articulated in *Ethex*, a complaint asserting a Lanham Act violation based on an implied claim of FDA approval cannot stand because it serves as a thinly veiled attempt to privately enforce the FDCA. Thus, Plaintiffs' Lanham Act claim is precluded in this instance and should be dismissed.

III. THE FDA HAS SOLE AUTHORITY TO DETERMINE WHETHER RAPID WEIGHT LOSS'S STATEMENTS ARE FALSE

A. The FDA Has Not Issued Any Interpretations of the FDCA Supporting The Conclusion That Rapid Weight Loss's Statements Are False

It is long-standing law that where a court would have to evaluate whether a defendant's challenged conduct is illegal by interpreting regulations that are the responsibility of an administrative agency, and that administrative agency has not issued any such interpretation, a Lanham Act claim cannot stand.

For example, in *Dial A Car, Inc. v. Transportation, Inc.*, 884 F. Supp. 584, 586 (D.D.C. 1995), a transportation company sued a number of cab companies under the Lanham Act, alleging that they made false and misleading statements, namely that the cab companies were "lawfully" (by local rule) able to offer customers the very same corporate services the private car company plaintiff provided, using the cab driver defendants' regular taxicabs. *Id.* at 591-92. The cab drivers moved to dismiss, arguing that there had been no misrepresentation because their statements were opinions about the legality of their services, that the accuracy of their statements were the purview of the local taxi commission's interpretation of DC regulations, and the taxi commission had not

determined whether taxicabs could provide corporate services. *Id.* at 592. In agreeing with the cab company defendants and dismissing the Lanham Act count, the court found that "[t]he only way for the Court to determine whether [defendant's challenged conduct] is illegal is by interpreting regulations that are within the Taxicab Commission's bailiwick." *Id.* But that taxi commission had never addressed the applicability (or non-applicability) of the relevant regulation as to defendants, and it is "generally inappropriate for a court in a Lanham Act case to determine preemptively how an administrative agency will interpret and enforce its own regulations and thereby to usurp the agency's responsibility for interpreting and enforcing potentially ambiguous regulations." *Id.* at 593.

Dial A Car was later affirmed by the D.C. Circuit. *Dial A Car v. Transp., Inc.*, 82 F.3d 484 (D.C. Cir. 1996). Notably, the D.C. Circuit went even further, finding that even if the taxi commission *subsequently* issued a clear statement of interpretation regarding whether the cab drivers could offer corporate services, it *still* would not be the federal court's place to find that the taxicab drivers' statements prior to the commission's interpretation could form the basis of a Lanham Act claim. *Id.* at 488-89. The "proper inquiry" was whether, at the time that the taxicab drivers made their statements, was there an unambiguous, clear interpretation from the taxi commission that those statements were false. *Id.* at 489. The holding of *Dial A Car* is equally applicable to the issue presented here. The FDA is the administrative agency responsible for interpreting and enforcing the FDCA and its regulations, including those relating to drug approvals. There has been no statement from FDA that Rapid Weight Loss's statements about semaglutide are false. Absent such a statement, this court would have to engage in an evaluation as to whether, under the FDCA, Rapid Weight Loss's multiple references to semaglutide and a single reference to Ozempic are permissible. Here, there is no ruling from the FDA that a reference to an API, like

semaglutide, implicates the relevant FDA approved drug (here, Ozempic), this court is not equipped to engage in that fact-finding itself. Thus, as there is no verifiable false statement of fact in Rapid Weight Loss's references to semaglutide and Ozempic, dismissal is required.

B. The FDA's Particular Expertise is Required to Interpret the FDCA, Precluding Plaintiffs' Lanham Act and SCUTPA Claims

Plaintiffs' Lanham Act claim also must fail because to determine whether Plaintiffs' allegations are true, FDA's "particular expertise" is required to interpret the FDCA, which precludes Plaintiffs from bringing the claim. *See Allergan USA Inc. v. Imprimis Pharm., Inc.*, No. SACV 17-1551-DOC (JDEx), 2018 WL 5919210, at *8 (C.D. Cal. Apr. 30, 2018) ("[C]laims regarding compliance with federal and state regulations dealing with requirements 'as to safety and . . . identity and strength, and . . . quality and purity characteristics' as well as contamination, quality control, sterility, and testing are likely precluded by the FDCA. . . . Lanham Act claims that require [ ] FDA's particular expertise or rulemaking authority are precluded."); *Allergan USA Inc. v. Imprimis Pharm., Inc.*, No. SACV 17-1551-DOC (JDEx), 2017 WL 10526121, at *7 (C.D. Cal. Nov. 14, 2017) ("[C]laims that directly implicate [ ] FDA's rulemaking authority, are not binary factual determinations, or involve an issue on which [ ] FDA has taken positive regulatory action are all likely precluded by [ ] FDA.") (internal quotation marks omitted); *Allergan*, 2017 WL 10526121, at *7 ("In short, the preclusion question turns on the specific nature of the claim in question—only claims where the law is unclear and [ ] FDA's particular expertise or rulemaking authority is required are precluded by the FDCA.").

Allergan stands for the principle that Lanham Act claims are precluded where the court cannot resolve such claims through binary factual determinations. *Allergan*, 2017 WL 10526121, at *7-8. Allergan brought an unfair competition and false advertising Lanham Act claim, alleging that a manufacturer, Imprimis, made false or misleading statements regarding Imprimis's compounded medications. *Id.* at *1. The court found that to resolve Allergan's claim, it need only make a binary

factual determination, *id.* at *7; it did not need to grapple with interpreting ambiguous agency statements. Specifically, because the plain language reading of Sections 503A and 503B of the FDCA prohibited Imprimis's actions the court was able to resolve Allergan's claim without needing to address "thorny questions that may require [ ] FDA's expertise." *Id.* In other words, the determinations facing the court were factual yes or no questions and did not involve tricky interpretations but references to clear, unambiguous sources. Did Imprimis mass-manufacture compound medications? Yes. Did Imprimis use ingredients not listed in the statute or the approved list? Yes. Did Imprimis exceed permitted quantities? Yes.

In contrast, here, no binary factual determination can resolve Plaintiffs' claim. Indeed, Plaintiffs' Lanham Act claim is inextricably intertwined with FDA's particular expertise. Plaintiffs allege that Rapid Weight Loss's referenced compounded medications (1) have not undergone safety and clinical trials like Ozempic, *see* Compl. ¶ 50; (2) are inferior in "safety, effectiveness, and quality" to Ozempic, *id.* ¶ 56; and (3) are not the same "semaglutide" as Ozempic, *id.* ¶ 38. Plainly, Plaintiffs' Lanham Act claim cannot be resolved without FDA's interpretation of the FDCA. As such, this case involves issues relating to the referenced compounded medications' safety, quality, and purity as compared to the FDA-approved Ozempic. Pursuant to *Allergan*, this type of technical and specialized determination rests squarely with the FDA. Put another way, the FDA's particular expertise is required to resolve Plaintiffs' claim regarding the referenced compounded medications' alleged inferiority in "safety, effectiveness, and quality" as compared to Ozempic. Because the FDA has sole authority to interpret and enforce the FDCA, Plaintiffs' Lanham Act claim is precluded and should be dismissed.

IV. PLAINTIFFS' SCUTPA CLAIM IS IMPLIEDLY PREEMPTED BY THE FDCA

The United States has sole enforcement authority of the FDCA. *See* 21 U.S.C. § 337(a). Thus,

parties may not bring private suit to enforce FDCA violations. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352-53 (2001) (determining that, because FDCA violations are prosecuted only by the United States, claims where violation of the statute was a "critical element" are impliedly preempted); *see also Nexus Pharm., Inc. v. Cent. Admixture Pharm. Servs.*, No. SACV 20-01506-CJC (JDEx), 2020 WL 6867069, at *2 (C.D. Cal. Nov. 18, 2020), *aff'd*, 48 F.4th 1040 (9th Cir. 2022) ("[I]f someone believes the FDCA is being violated, a private lawsuit is generally not the way to address it. . . . [P]rivate enforcement of the [FDCA] is barred[.]"). If a claim depends on the existence of the FDCA, then the claim is impliedly preempted by the FDCA because only the FDA can interpret the FDCA. *Exela Pharma Scis., LLC v. Sandoz, Inc.*, 486 F. Supp. 3d 1001, 1012 (W.D.N.C. 2020) ("'The test for determining whether a state law claim is impliedly preempted is whether or not the claim would exist in the absence of the FDCA.'") (quoting *Evans v. Rich*, No. 5:13-cv-868-BO, 2014 WL 2535221, at *2 (E.D.N.C. June 5, 2014)); *Ellis v. Smith & Nephew, Inc.*, 2016 U.S. Dist. LEXIS 193607, *20 (D.S.C. Feb. 16, 2016) (finding SCUTPA claim preempted by the FDCA). Thus, for Plaintiffs' SCUTPA claim to survive FDCA preemption, the claim must have an independent state law basis—meaning, an independent basis for why the claim is misleading or deceptive that cannot rest on the existence of the FDCA. *See Exela Pharma Scis.*, 486 F. Supp. 3d at 1012. Plaintiffs' claim fails to meet this burden.

As set forth above, Plaintiffs' Complaint is riddled with allegations that hinge on the FDA's enforcement and interpretation of the FDCA. To resolve whether Plaintiffs' SCUTPA claim is misleading or false regarding the referenced compounded medications' composition, safety, and purity, FDA's interpretation of the FDCA is required. Plaintiffs' SCUTPA claim fails for the same reasons articulated above—to determine whether Plaintiffs' allegations are true, the FDA, in its sole authority, must use its "particular expertise" to interpret the FDCA, which preempts Plaintiffs from bringing the claim.

Further, several federal courts have already found these very same Plaintiffs are trying to use these types of suits as a mechanism to enforce the FDCA against private parties and have preempted Plaintiffs' claims on these grounds. In *Novo Nordisk, Inc. v. Brooksville Pharm. Inc.*, No. 8:23-cv-1503-WFJ-TGW, 2023 WL 738519 (M.D. Fla. Nov. 8, 2023), these same Plaintiffs sued a compounding pharmacy, alleging that the pharmacy manufactured and sold to the public drugs containing semaglutide without FDA approval in violation of the Florida Drug and Cosmetics Act and Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"). *Brooksville*, 2023 WL 738519, at *1. The court explained that "where the existence of [the FDCA] is a critical element of a case, the claim is impliedly preempted." *Id.* at *3 (internal quotation marks omitted).

These same Plaintiffs relied on three Eleventh Circuit cases to show that state law claims based on conduct that violates the FDCA are not preempted where the wrongdoing gives rise to liability under state law even if the FDCA did not exist. *Id.* at *2 (citing *Jacob v. Mentor Worldwide, LLC*, 40 F.4th 1329, 1336 (11th Cir. 2022); *Godelia v. Doe 1*, 881 F.3d 1309, 1320 (11th Cir. 2018); *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1330 (11th Cir. 2017)). However, the court was not persuaded by Plaintiffs' argument and held that "Plaintiffs' claim, as written, is that Plaintiffs suffer economic loss due to Defendant's violation of the Florida Drug and Cosmetic Act, which is itself a law that says in substance [to] comply with the FDCA. . . . The Court can identify no alleged conduct that would give rise to liability under state law even if the [FDCA] did not exist." *Brooksville*, 2023 WL 738519, at *3. Thus, the court found that Plaintiffs' claim was preempted by the FDCA and granted Brooksville's motion to dismiss. *Id.* at *4.

Similarly, in *Novo Nordisk, Inc. v. WellHealth Inc.*, 3:23-cv-00782-ACC-LLL, 2025 WL 699769 (M.D. Fla. Jan. 30, 2025), these same Plaintiffs alleged that WellHealth jeopardized the public health by selling drugs without adequate FDA or Florida premarket regulatory approval.

WellHealth, 2025 WL 699769 at *1. WellHealth moved to dismiss and claimed that Plaintiffs' claim was preempted by the FDCA. *Id.* WellHealth argued that the FDA has sole authority to enforce or restrain the violations of the FDCA, and Plaintiffs argued that preemption is inapplicable where an alleged wrongdoing "gives rise to liability under state law even if the FDCA did not exist." *Id.* at *3-4. The court, citing Supreme Court precedent, explained that a plaintiff cannot seek to privately enforce a duty that is owed to FDA and reiterated that to avoid preemption, "claims must be based not on the FDCA, but on common law or traditional state tort law [that] predated the federal law in question." *Id.* (citing *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 109 (2014); *Buckman Co.*, 531 U.S. at 352-53)) (internal quotation marks omitted).

As in *Brooksville*, the *WellHealth* Plaintiffs relied on *Jacob*, *Godelia*, and *Mink*, but the court was not persuaded and held that "the existence of the FDCA is a critical element of [the claims] and is impliedly preempted." *Id.* at *2-5; *see also Novo Nordisk Inc. v. Live Well Drugstore, LLC*, No. 3:23-cv-808-ACC-PDB, ECF No. 85, pp. 12–14 (M.D. Fla. Jan. 30, 2025) (citing *Brooksville* and holding plaintiffs' claims are preempted because the claims are an attempt to unlawfully bring a private action to enforce FDCA compliance, which solely rests within FDA's authority); *Novo Nordisk Inc. v. Wells Pharmacy Network, LLC*, No. 5:23-cv-00689-ACC-PRL, ECF No. 48, pp. 16-17 (M.D. Fla. Feb. 12, 2025) (noting that while Wells Pharmacy did not seek dismissal on preemption grounds, "similar [FDUTPA] lawsuits have been dismissed on preemption grounds, and preemption would likely apply here").

As with Plaintiffs' above-referenced cases in Florida, Plaintiffs' SCUTPA claim is preempted on the same grounds, and therefore the SCUTPA claim should be dismissed.

CONCLUSION

It is for the foregoing reasons that this Court should grant this Motion to Dismiss and

dismiss Plaintiffs' Complaint with prejudice.

Respectfully submitted this 24th day of March, 2025,

By: s/ *Wesley T. Moran*

NELSON MULLINS RILEY & SCARBOROUGH LLP

Wesley T. Moran
Federal Bar No. 12797
E-Mail: wes.moran@nelsonmullins.com
3751 Robert M Grissom Pkwy #300,
Myrtle Beach, SC 29577
(843) 448-3500
John C. McElwaine
Federal Bar No. 6710
E-Mail: john.mcelwaine@nelsonmullins.com
Sarah Specter Powell
Federal Bar No. 13342
E-Mail: sarah.powell@nelsonmullins.com
151 Meeting Street, Suite 600
Charleston, SC 29401
(843) 853-5200

BLANK ROME LLP

Rachael G. Pontikes (*pro hac vice* forthcoming)
E-Mail: rachael.pontikes@blankrome.com
444 West Lake Street, Suite 1650
Chicago, IL 60606
(312) 776-2587
Shannon McClure Roberts (*pro hac vice* forthcoming)
E-Mail: Shannon.mcclure@blankrome.com
One Logan Square
130 North 18th Street
Philadelphia, PA 19103
(215) 569-5586

Attorneys for Rapid Weight Loss And Esthetics Center, Inc.